

TECNIS iTec Preloaded Delivery System

Predictability ■ Efficiency ■ Safety ■ High-Quality Visual Outcomes

■ PLUNGER MARKINGS

Provide clear guidance to ensure consistent delivery

■ SCREW-STYLE INSERTION MECHANISM

Ensures consistent, controlled advance and delivery of the IOL

■ PRODUCT LABELING

Allows verification of lens model and power prior to implantation

■ Preloaded with TECNIS® 1-Piece IOL

■ 2.2 mm–2.4 mm incision

■ Screw-style insertion

■ Latex-free

■ BEVEL TIP

Enables planar delivery via a 2.2 mm–2.4 mm incision

■ VIEWING WINDOW

Facilitates visual check of IOL and OVD

Indications: The TECNIS® 1-Piece Intraocular Lens (IOL) is indicated for the visual correction of aphakia in adult patients in whom a cataractous lens has been removed by extracapsular cataract extraction. This device is intended to be placed in the capsular bag. See Important Safety Information on the back page.

TECNIS®
ASPHERIC IOL



Monofocal

with TECNIS iTec Preloaded Delivery System

Abbott
A Promise for Life



TECNIS iTec Preloaded Delivery System (PCB00)

| | |
|------------------|---------------|
| Incision Size: | 2.2 mm–2.4 mm |
| Delivery System: | Screw-style |
| Injector Type: | Disposable |

TECNIS® 1-Piece Monofocal IOL

OPTIC CHARACTERISTICS

| | |
|-------------------|--|
| Power Range: | +5.0 D to +34.0 D in 0.5 diopter increments |
| Diameter: | 6.0 mm |
| Shape: | Biconvex, anterior aspheric surface, square optic edge |
| Material: | UV-blocking hydrophobic acrylic |
| Refractive Index: | 1.47 |
| Edge Design: | ProTEC frosted, continuous 360° posterior square edge |

BIOMETRY

| | |
|-------------|--------------------------------------|
| A-constant: | 119.3 (Optical Biometry)* |
| | 118.8 (Ultrasound Biometry-Contact)† |

HAPTIC CHARACTERISTICS

| | |
|-----------------|---------------------------------|
| Overall Length: | 13.0 mm |
| Style: | C |
| Material: | UV-blocking hydrophobic acrylic |
| Design: | Haptics offset from optic |

*Derived from clinical evaluation results of the TECNIS® 1-Piece IOL platform.

†Value theoretically derived for a typical 20.0 D lens. Abbott Medical Optics recommends that surgeons personalize their A-constant based on their surgical techniques and equipment, experience with the lens model, and postoperative results.

Experience the advantages of the TECNIS iTec Preloaded Delivery System in your OR today.

Visit www.tecnisiol.com or call 1-877-AMO-4-LIFE.



Important Safety Information—TECNIS® 1-Piece IOL with the TECNIS iTec Preloaded Delivery System

Indications: The TECNIS® 1-Piece Intraocular Lens (IOL) is indicated for the visual correction of aphakia in adult patients in whom a cataractous lens has been removed by extracapsular cataract extraction. This device is intended to be placed in the capsular bag.

Warnings: Physicians considering lens implantation should weigh the potential risk/benefit ratio for any conditions described in the TECNIS® 1-Piece IOL with the TECNIS iTec Preloaded Delivery System Directions for Use that could increase complications or impact patient outcomes. Do not push the plunger forward to fully advance the lens until ready for lens implantation. Discard the device if the lens has been fully advanced for more than 1 minute. The TECNIS® 1-Piece IOL should not be placed in the ciliary sulcus. Use of methylcellulose viscoelastics is not recommended.

Precautions: The use of viscoelastics is required when using the TECNIS iTec Preloaded Delivery System. Do not use if the TECNIS iTec Preloaded Delivery System has been dropped or if any part was inadvertently struck while outside the shipping case. Do not reuse, resterilize, or autoclave.

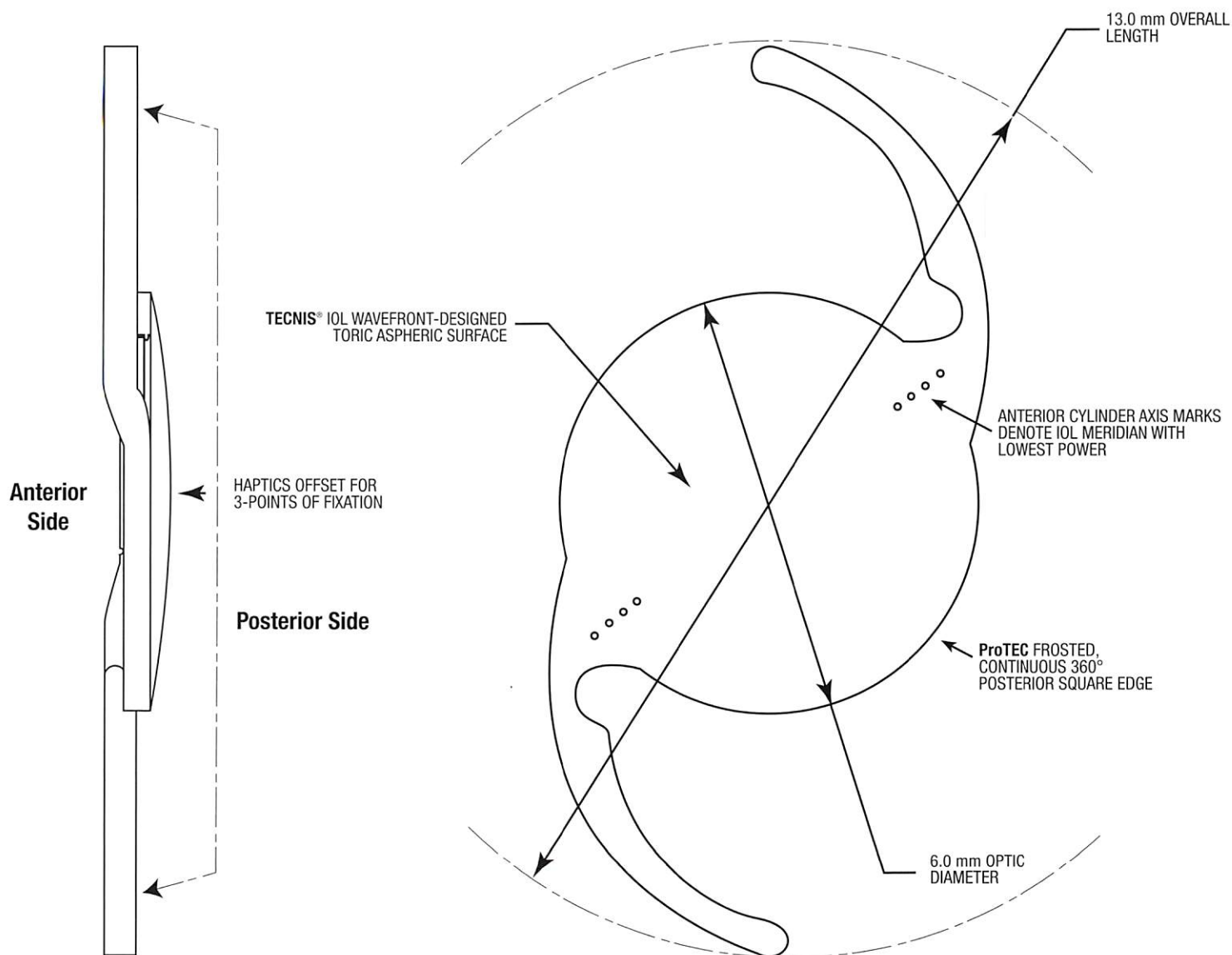
Adverse Events: The most frequently reported adverse event that occurred during the clinical trial of the 1-Piece IOL was macular edema, which occurred at a rate of 3.3%. Other reported reactions occurring in less than 1% of patients were secondary surgical intervention (pars plana vitrectomy with membrane peel) and lens exchange (due to torn lens haptic).

Caution: Federal law restricts this device to sale by or on the order of a physician.

Attention: Reference the Directions for Use labeling for a complete listing of Indications, Warnings and Precautions.

TECNIS® Toric 1-Piece Aspheric IOL

Hydrophobic Acrylic



| OPTIC CHARACTERISTICS | | | | | | | |
|--|-----------------|-----------------|-----------------|---|-----------------|-----------------|-----------------|
| Powers: | | | | +5.0 D to +34.0 D in 0.5 diopter increments | | | |
| MODEL | ZCT150 | ZCT225 | ZCT300 | ZCT400 | ZCT450 | ZCT525 | ZCT600 |
| Cylinder Powers – IOL Plane: | 1.50 D | 2.25 D | 3.00 D | 4.00 D | 4.50 D | 5.25 D | 6.00 D |
| Cylinder Powers – Corneal Plane:* | 1.03 D | 1.54 D | 2.06 D | 2.74 D | 3.08 D | 3.60 D | 4.11 D |
| Corneal Astigmatism Correction Range¹ (Preop Kcyl+SIA) | 0.75 D – 1.50 D | 1.50 D – 2.00 D | 2.00 D – 2.75 D | 2.75 D – 3.25 D | 3.00 D – 3.50 D | 3.50 D – 4.00 D | 4.00 D – 4.75 D |
| Diameter: | | | | 6.0 mm | | | |
| Shape: | | | | Biconvex, anterior toric aspheric surface | | | |
| Material: | | | | UV-blocking hydrophobic acrylic | | | |
| Refractive Index: | | | | 1.47 at 35° C | | | |
| Edge Design: | | | | ProTEC frosted, continuous 360° posterior square edge | | | |
| OPTICAL BIOMETRY¹ | | | | | | | |
| A-Constant: | | | | 119.3 | | | |
| AC Depth: | | | | 5.7 mm | | | |
| Surgeon Factor: | | | | 1.96 mm | | | |
| APPLANATION ULTRASOUND BIOMETRY² | | | | | | | |
| A-Constant: | | | | 118.8 | | | |
| Theoretical AC Depth: | | | | 5.4 mm | | | |
| Surgeon Factor:¹ | | | | 1.68 mm | | | |
| HAPTIC CHARACTERISTICS | | | | | | | |
| Overall Length: | | | | 13.0 mm | | | |
| Configuration: | | | | Tri-Fix design, modified C, integral with optic | | | |
| Material: | | | | UV-blocking hydrophobic acrylic | | | |
| Design: | | | | Haptics offset from optic | | | |
| RECOMMENDED INSERTION INSTRUMENTS | | | | MODEL | | | |
| The UNFOLDER® Platinum 1 Series Handpiece | | | | DK7796 | | | |
| The UNFOLDER® Platinum 1 Series Cartridge | | | | 1MTEC30 | | | |

* Based on average pseudophakic human eye and Holladay et al. A three-part system for refining intraocular lens power calculations. *J Cataract Refract Surg* 1988;14(1):17-24.

† Based on a vector sum of preoperative corneal astigmatism (preop Kcyl) and the predicted effect of surgically induced astigmatism (SIA).

‡ Derived from clinical evaluation results of the 1-Piece IOL Platform for optical biometry.

§ A-Constant theoretically derived for ultrasound biometry.

To learn more and to view important safety information, please visit
www.TECNISToricCalc.com. Or call 1-877-AMO-4-LIFE.

INDICATIONS AND IMPORTANT SAFETY INFORMATION

Rx Only

ATTENTION

Reference the Directions for Use labeling for a complete listing of Indications

INDICATIONS

The TECNIS Toric 1-Piece posterior chamber lens is indicated for the visual correction of aphakia and pre-existing corneal astigmatism of one diopter or greater in adult patients with or without presbyopia in whom a cataractous lens has been removed by phacoemulsification and who desire improved uncorrected distance vision, reduction in residual refractive cylinder, and increased spectacle independence for distance vision. The device is intended to be placed in the capsular bag.

WARNINGS

Physicians considering lens implantation should weigh the potential risk/benefit ratio for any circumstances described in the TECNIS Toric 1-Piece IOL Directions for Use that could increase complications or impact patient outcomes. The clinical study did not show evidence of effectiveness for the treatment of preoperative corneal astigmatism of less than one diopter. The TECNIS Toric 1-Piece IOL should not be placed in the ciliary sulcus. Rotation of the TECNIS Toric 1-Piece IOL away from its intended axis can reduce its astigmatic correction. Misalignment greater than 30° may increase postoperative refractive cylinder.

PRECAUTIONS

Accurate keratometry and biometry in addition to the use of the TECNIS Toric Calculator (www.TecnisToricCalc.com) are recommended to achieve optimal visual outcomes. The safety and effectiveness of the toric intraocular lens have not been substantiated in patients with certain preexisting ocular conditions and intraoperative complications. Refer to the TECNIS Toric 1-Piece IOL Directions for Use for a complete description of the preexisting conditions and intraoperative complications. All preoperative surgical parameters are important when choosing a toric lens for implantation. Variability in any of the preoperative measurements can influence patient outcomes. All corneal incisions were placed temporally in the clinical study. When the insertion system is used improperly, the haptics of the TECNIS Toric 1-Piece IOL may become broken. Please refer to the specific instructions for use provided with the insertion instrument or system. Do not reuse, resterilize, or autoclave.

ADVERSE EVENTS

The most frequently reported cumulative adverse event that occurred during the TECNIS Toric 1-Piece IOL clinical trial was surgical re-intervention which occurred at a rate of 3.4% (lens repositioning procedures and retinal repair procedures).

1. Calculated based on Holladay I formula: Holladay JT, Prager TC, Chandler TY, Musgrove KH, Lewis JW, Ruiz RS. A three-part system for refining intraocular lens power calculations. *J Cataract Refract Surg*. 1988;14(1):17-24 and Holladay, J.T. International Intraocular Lens & Implant registry 2003. *J Cataract Refract Surg*. 2003; 29:176-197.

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PP2015CT0749

Reorder: TEC13-04